IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

Kathryn Kiker, et al., Plaintiffs, vs. SmithKline Beecham Corporation d/b/a GlaxoSmithKline LLC, Defendant.	:	Case No. 2:14-cv-02164-EAS-TPK Chief Judge Edmund A. Sargus, Jr. Magistrate Judge Terence P. Kemp

DEFENDANT GLAXOSMITHKLINE LLC'S MOTION *IN LIMINE* TO EXCLUDE REFERENCE TO OR ARGUMENT THAT GSK DESTROYED RAW DATA FROM EARLY ANIMAL STUDIES ON PAXIL IN 1993
(ORAL ARGUMENT REQUESTED)

Defendant GlaxoSmithKline LLC ("GSK") submits its Motion *in Limine* to Exclude Reference to or Argument that GSK Destroyed Raw Data from Early Animal Studies on Paxil in 1993.

I. INTRODUCTION

This product liability case involves two primary issues: (1) whether Kathryn Kiker's alleged use of the prescription antidepressant Paxil® ("Paxil") during the first trimester of her pregnancy in 2000 caused C.S. to develop a ventricular septal defect ("VSD"); and (2) whether Paxil's labeling about use during pregnancy was adequate when Dr. Julie Guthrie prescribed Paxil to Ms. Kiker in 2000.

GSK anticipates that Plaintiffs will attempt to distract and prejudice the jury by arguing that GSK destroyed the "raw data" from its Paxil pre-clinical animal studies, falsely insinuating that this was done to cover-up Paxil's teratogenic potential. This red herring has no relevance to any core issue in this case. Further, Plaintiffs' claim is false, grossly distorts the regulatory

practices in place at the time, and should be excluded because it is enormously prejudicial. ***In fact, the last court to try a Paxil pregnancy case ruled that the plaintiffs were "precluded from arguing that Defendant [GSK] destroyed the evidence [raw data from animal studies] or intimating spoliation on the part of the Defendant."*** (*Rader v. GSK*, Case No. 3672 (Phila. Ct. Com. Pl.), Mar. 21, 2016 Order at Subpart 2 (emphasis added) (attached as Ex. 1).[1])

II. ARGUMENT

A. GSK Retained Its Raw Data in Accordance with FDA Regulations; Further, the Presence Or Absence of Raw Data Has Zero Effect on One's Ability to Review And Evaluate the Results of the Paxil Animal Studies.

Whether GSK maintained the raw data[2] from its pre-clinical animal studies is a manufactured controversy that has nothing to do with the merits of this case. Plaintiffs' only plausible purpose for trying to inject this issue into trial is to distract, mislead, and prejudice the jury. Three facts show the hollowness of this issue.

First, GSK not only met but exceeded the retention policies for raw data required by FDA regulations. Under the FDA's Good Laboratory Practices ("GLP") raw data pertaining to a nonclinical study (*i.e.*, animal studies) must be retained for five years from the date the information is first submitted to the regulatory agency. *See* 21 C.F.R. § 58.195(b)(2) (data must be retained for a "period of at least 5 years following the date of which the results of the non-clinical laboratory study are submitted to the FDA in support of an application for a research or

[1] For the convenience of the Court, exhibits are attached to the Declaration of William D. Kloss, Jr., accompanying this Motion.

[2] In the context of pre-clinical animal studies conducted in the late 1970s and early 1980s, "raw data" consists of the researchers' original laboratory notebooks: "It's important to realize we're talking about 1979. We did not have -- laboratories didn't have computerized data collection systems. The scientists were literally writing down their results in notebooks or on paper, on forms and such. And so when the report is made, somebody has to actually type those results into a document and that's what we call the report. When I'm asked about raw data, what I think about is those original notebooks where everything is written down. That's the raw information, if you will." (Trial Test. of Patrick Wier in *Rader v. GSK*, Mar. 30, 2016 a.m. Trial Tr. [hereinafter "Wier *Rader* Test."] at 89:14 – 89:25 (relevant excerpts attached as Ex. 2).)

marketing permit"). The pre-clinical animal studies for Paxil were submitted to FDA in the Notice of Claimed Investigation Exemption for a New Drug on December 21, 1983. (*See* Dec. 21, 1983 Letter from Lawrence P. Olon, J.D., Beecham Laboratories to FDA re: Notice of Claimed Investigational Exemption For a New Drug – Paroxetine Tablets (BRL 29060A) (attached as Ex. 3).) Therefore, FDA regulations required GSK to retain the data until December 21, 1988, and any allegation that GSK improperly destroyed raw data in 1993 is wrong as a matter of law. Indeed, GSK exceeded FDA regulations requiring the retention of such data by a factor of 2.

Second, whether GSK kept or destroyed the raw data from the animal studies has no effect on the ability to evaluate and interpret the Paxil animal studies <u>because the final reports capturing that very data exist.</u> Indeed, Plaintiffs' own expert Dr. Laura Plunkett evaluated the early animal studies performed on Paxil, without reviewing the raw data – and she was able to opine about Paxil's purported teratogenicity by reviewing the final reports prepared directly from that raw data. (*See* Report of Laura Plunkett, Ph.D., at 11-18 (excerpts attached as Ex. 4).) As Dr. Plunkett's report shows, not having access to raw data in no way prevents her or anyone else from evaluating the results of those studies even today.

Third, access to the original research notebooks is unnecessary because a Quality Assurance Unit has independently reviewed each of the Paxil teratology animal studies and verified that the raw data in the original notebooks <u>matches</u> that shown in the final reports. As Dr. Patrick Wier explained in the *Rader* trial:

> That's the raw information, if you will. And that gets typed up in the report. There is a separate group of people whose job it is, quality assurance job, to actually check those written records, the handwritten records, with what is typed in the report to make sure that the typed report, the information there is the same as what the scientists wrote down in the laboratory. They do that independent

> of the study authors and they issue a statement. This is what is showing here. QAU stands for Quality Assurance Unit. And that sits on top of the report to say somebody has independently checked and the data that you're looking at in this typed document is the same as what those scientists wrote down in their notebooks.

(Ex. 2, Wier *Rader* Test. at 89:24 – 90:14.) The Quality Assurance Unit certification can be seen on the second page of each of the three teratology animal studies for Paxil.[3] Thus, any evidence or argument that GSK has "destroyed" the "raw data" for its Paxil animal studies is misleading and meaningless, designed to suggest a non-existent nefarious purpose.

B. Evidence Regarding the Destruction of the Raw Data Is Irrelevant And Should Be Excluded.

Any evidence regarding GSK's 1993 destruction of raw data from the early Paxil animal studies is irrelevant to this case. *See* FED. R. EVID. 401 (evidence is relevant if it has any tendency to make a fact of consequence more or less probable than it would be without the evidence). As shown above, the lack of "raw data" cannot show any malfeasance on GSK's part because GSK far exceeded the applicable FDA regulations that govern raw data retention. Second, the lack of "raw data" does not hinder anyone's ability to interpret or evaluate the Paxil animal studies, in fact, Plaintiffs' expert has already done just that without having access to this "raw data." Third, the lack of "raw data" has no practical relevance because an independent Quality Assurance Unit has previously verified the fidelity of the data contained in the Paxil teratology animal studies, obviating the need for the original research notebooks. Given this lack of relevance, any such evidence should be excluded. FED. R. EVID. 402; *see also Koloda v. General Motors Parts Div., General Motors Corp.*, 716 F.2d 373, 375 (6th Cir. 1983)

[3] (*See* "Paroxetine Fertility and General Reproductive Performance Study in the Rat," Apr. 27, 1981 at PAR060000308 (attached as Ex. 5); "Paroxetine Teratology Study in the Rat," Apr. 27, 1981 at PAR060000566 (attached as Ex. 6); "Paroxetine Teratology Study in the New Zealand White Rabbit," Apr. 27, 1981 at PAR041223288 (attached as Ex. 7).)

("Relevancy is the threshold determination in any decision regarding the admissibility of evidence; if evidence is not relevant, it is not admissible.").

C. Any Slight Probative Value Attached to This Evidence Is Outweighed by the Danger of Creating Unfair Prejudice, Confusing the Issues, Misleading the Jury, And Wasting Time.

Even if this evidence has some probative value – which it does not – the probative value is so slight that it is far outweighed by the danger of creating unfair prejudice to GSK, confusing the jury, misleading the jury, and wasting the time of the Court and the parties. *See* FED. R. EVID. 403 (evidence may be excluded "if its probative value is substantially outweighed by a danger of … unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence"); *United States v. Vance*, 871 F.2d 572, 576 (6th Cir. 1989). When evidence's probative value, if any, is substantially outweighed by the risk of unfair prejudice, it should be excluded. *United States v. Gibbs*, 797 F.3d 416, 422 (6th Cir. 2015). Evidence is unfairly prejudicial if it "tends to lead jurors to make a decision on an improper basis." *United States v. Ford*, 761 F.3d 641, 648 (6th Cir. 2014); *Koloda*, 716 F.2d at 377-78 (evidence is inadmissible under Rule 403 if it requires "a foray into collateral matters damaging to plaintiff's interests or appeal[s] to the emotions or prejudices of the jurors.").

Evidence or allegations regarding GSK's 1993 destruction of the raw data from the early Paxil animal studies would run afoul of Federal Rule of Evidence 403 because it introduces highly misleading issues into the proceedings. The introduction of such evidence likely would confuse and mislead the jury regarding whether GSK acted appropriately and in compliance with the GLPs in destroying the data in 1993. Indeed, there is a real risk that a jury might mistakenly believe that GSK violated FDA regulations or standard practices when it discarded the original notebooks; that GSK may have been attempting to cover-up unfavorable results; or that Plaintiffs

have been hindered in bringing their lawsuit. All of these conjectures are false, and, if a jury somehow reached any such conclusion, the prejudice to GSK would be enormous.

In addition, the introduction of this evidence would waste valuable time. Absent exclusion, Plaintiffs will spend considerable time presenting evidence regarding GSK's destruction of the raw data in 1993. In response GSK will be required to explain the GLPs, how GSK complied with the guidelines, and what data from the early Paxil animal studies still exists and was reviewed by Plaintiffs' expert. The presentations of this evidence will likely add significant time to trial; time that does not increase the likelihood of the jury reaching a just result. *See Koloda*, 716 F.2d at 377-78 (evidence is inadmissible under Rule 403 if it requires "a foray into collateral matters damaging to plaintiff's interests ….").

III. CONCLUSION

For the foregoing reasons, GSK respectfully requests that this Court grant its Motion *in Limine* and enter an order excluding references to or arguments that GSK destroyed raw data from early animal studies on Paxil in 1993.

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CERTIFICATE OF SERVICE

This is to certify that a copy of the foregoing was served upon all counsel of record, this 24th day of January, 2017, by the Court's electronic service.

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Kathryn Kiker, et al.,	:	
	:	
Plaintiffs,	:	
	:	Case No. 2:14-cv-02164-EAS-TPK
vs.	:	
	:	
SmithKline Beecham Corporation d/b/a GlaxoSmithKline LLC,	:	Chief Judge Edmund A. Sargus, Jr. Magistrate Judge Terence P. Kemp
	:	
Defendant.	:	
	:	

ORDER

AND NOW, this ____ day of _____, 2017, upon consideration of the Motion *in Limine* to Exclude Reference to or Argument that GSK Destroyed Raw Data from Early Animal Studies on Paxil in 1993 filed by Defendant GlaxoSmithKline LLC, and any response or reply thereto, and having considered the arguments of counsel, it is hereby ORDERED that Defendant's Motion is GRANTED.

_____ _____

Date Edmund A. Sargus, Jr.
Chief United States District Judge